FOCUS-EU

HEALTH

November 2019

Overview of EU and global policy developments

2020 EU budget

Negotiations between the EU Council, the European Parliament and the European Commission led to an agreed €13.5 billion budget (+8.8%) for the final year of the Horizon 2020 research programme. The Commission had originally planned a budget of €13.2 billion, up from €12.4 billion in 2019. Erasmus+ will also receive €2.9 billion (+3.6%) to support youth exchanges.

In general the EU budget for 2020 strongly focuses on growth and competitiveness, climate action and other EU priorities such as security and management of migration. Total commitments are set at €168.7 billion. This is an increase of 1.5% compared to the 2019 budget as amended. €1.5 billion have been kept available under the expenditure ceilings of the multi-annual financial framework for 2014-2020, allowing the EU to react to unforeseeable needs. Total payments amount to €153.6 billion, rising 3.4% from 2019. This increase reflects the continuing implementation of the 2014-2020 programmes at full speed. The agreed figures are based on the premise that the UK will continue to participate fully in the financing and implementation of the EU budget for 2020.

Source: https://www.consilium.europa.eu/budget-agreement/

European Council

New list of Commissioner candidates

The European Council has adopted a new list of persons whom it proposes for appointment as members of the Commission until 31 October 2024.

Source:
https://www.consilium.europa.eu/commissioner-candidates/

Economy of Wellbeing

The Council has adopted conclusions on the Economy of Wellbeing inviting the member states and the Commission to include an economy of wellbeing perspective horizontally in national and Union policies and to put people and their wellbeing at the centre of policy design.

Source: https://www.consilium.europa.eu/economy-of-wellbeing

European Commission

Updated Guidance on Clinical Trial Regulation

The European Commission (EC) has issued updated guidance on the incoming clinical trials regulation and more specifically on requests for information (RFIs); on making clinical trial assessment reports public and on the sponsor's responsibilities regarding changes to a clinical trial that are not substantial modifications but are relevant for supervising the trial.

Source: CLINICAL TRIALS REGULATION (EU) NO 536/2014

Further read: https://www.raps.org//2019/11/clinical-trial-regula

Medicines subject to additional monitoring

A joint report has been issued by the Heads of Medicines Agencies (HMA) and EMA on the experience of the Member States and EMA on additional monitoring in the three years after the introduction of the black triangle in 2013. The HMA/EMA report that patients and healthcare professional groups had knowledge of the concept of additional monitoring, although the level of understanding varied. There is a misunderstanding about the reasons for a medicine being subject to additional monitoring. A survey of Member States reports that in some cases the inclusion of medicines with an imposed PASS in the additional monitoring list leads to a large number of medicines which have been on the market for many years being subject to additional monitoring. Some Member States questioned the added value in these cases and the possibility for misunderstanding the reason for inclusion of the black triangle in the product information. It was also mentioned that confusion can be created when products with the same active substance are not always subject to additional monitoring.
The Commission does not consider that these concerns require an immediate review of the legislation. Member States and EMA are encouraged to continue promoting ADR reporting and sharing their experience to further develop best practices and to continue to collect evidence to strengthen the evidence base for future review of the scheme.

***Black Triangle**: Since 2013, a black triangle is placed on the patient information leaflets and the Summary of Product Characteristics of medicinal products which are subject to additional monitoring in the EU. The black triangle aims* to highlight the importance of reporting ADRs in general and it *should be accompanied by a text encouraging patients and healthcare professionals to report any unexpected adverse events experienced in the treatment with these products.*

***PASS** (Post-Authorisation Safety Study) is a study that is carried out after a medicine has been authorised to evaluate the safety and benefit-risk profile of a medicine for regulatory decision-making. PASSs can either be clinical trials or non-interventional studies. In December 2016 the list of medicines under additional monitoring included a total of 2099 medicines, 88% of which were because of an imposed PASS.*

Source: https://eur-lex.europa.eu/

EUDAMED

The European Commission has announced that the launch of EUDAMED will be done together for medical and in-vitro medical devices, at the original date foreseen for in-vitro medical devices i.e. May 2022. The Commission concluded that it will only be possible to make EUDAMED operational once the entire system and its different modules have achieved full functionality and have been subject to an independent audit. The date of application of the MDR remains May 2020.

EUDAMED is the new multipurpose database for medical devices to improve transparency and coordination of information regarding medical devices available on the EU market. It will contain different modules on actors, UDI & devices, notified bodies & certificates, vigilance, clinical investigations and performance studies and market surveillance. It will also function as a dissemination system (open to the public), and will be interoperable.

Source: https://ec.europa.eu/growth/eudamed_en

Across the World

FDA - Generic drug Guidances

The US Food and Drug Administration (FDA) has released 105 product-specific guidance documents to aid generic drug development, including 27 new draft guidances and 78 revised draft guidances. The guidances intend to promote generic competition by clarifying FDA's expectations for the studies required to demonstrate that a generic drug is equivalent to a reference listed drug.

Source: https://s3.amazonaws.com/public-inspection.FDA.pdf

Health Canada Creates New Medical Devices Directorate

A RAPS article by Zachary Brennan on the creation of a new Canadian Medical Devices Directorate that takes a lifecycle approach by bringing together postmarket functions currently led by the Marketed Health Products Directorate and the pre-market functions of the Therapeutic Products Directorate. The directorate will include 165 positions and a budget of $15.85 million funded through resource transfers and reallocation within Canada's Health Products and Food Branch.

Sources: https://www.raps.org/canada-medical-devices-director

IGBA Calls for Regulatory Convergence on Biosimilars

A RAPS article by Zachary Brennan on the International Generic and Biosimilar medicines Association (IGBA) calling for a global framework for biosimilar development particularly on the acceptance of foreign-sourced reference products. The IGBA calls also for more transparency on clusters, the collaboration areas between the FDA and EMA on special topics and therapeutic areas identified as requiring an intensified exchange of information and collaboration.
Source: https://www.raps.org/regulatory-convergence-on-b

Other

Country Health Profiles

Experts from the OECD and the Observatory prepared a set of 30 Country Health Profiles, covering all EU Member States, as well as Iceland and Norway. The *State of Health in the EU*'s Country Health Profiles are designed to be a one-stop-shop for knowledge and information on a country's health system, put into the perspective of a cross-EU comparison.

Access your country's profile: https://ec.europa.country_profiles

Global AI expert council

Canada and France have announced the launch of the *International Panel on Artificial Intelligence (IPAI)*. The *IPAI* mission will be to support and guide the responsible adoption of AI that is human-centric and grounded in human rights, inclusion, diversity, innovation and economic growth. The panel will facilitate international collaboration in a multistakeholder manner with the scientific community, industry, civil society, related international organizations, and governments.
The mandate will cover areas such as:

1 Data Collection and Access
2 Data Control and Privacy
3 Trust in AI
4 Acceptance and Adoption of AI
5 Future of Work
6 Governance, Laws and Justice
7 Responsible AI and Human Rights
8 Equity, Responsibility and Public Good

Sources: https://pm.gc.ca/en/-international-panel-AI
https://sciencebusiness.net/global-ai-expert-council

EMA: Relocation by 2020

EMA staff will move into their new permanent offices and workspaces in Amsterdam in January 2020. The Brexit-related relocation of EMA"s headquarters to Amsterdam and other activities cost the European Medicines Agency (EMA) €59.6 million ($66 million) in 2019. EMA is working on a scenario in which the UK will become a third country and no longer will engage as (co)-rapporteur for new marketing authorisation applications via the centralized procedure. EMA's total available workforce in Amsterdam is about 730, which is about 20% less than the London workforce. EMA is currently reviewing its organisational structure with view to set up task forces that focus on key priorities such as digital transformation and regulatory science. Other activities include redistributing the UK's portfolio of over 370 centrally authorized products to rapporteurs and co-rapporteurs in preparation for Brexit. EMA announced that the centrally authorized medicines for which there are concerns of Brexit-related supply disruptions is decreasing.

Source: https://www.ema.europa.eu/brexit
https://www.ema.europa.eu/budget-no-1-2019

EMBO: Plan S and publishing costs

The European Molecular Biology Organisation has released its publishing costs and has *called for the need for a better understanding of the* article-processing charges (APCs) in *science publishing* for Open Access. The analysis covers four of EMBO's five journals and reveals that, in 2017, their total revenue was almost €6 million. Subscriptions generated nearly €4 million of this, with the remaining revenue consisting mainly of article processing charges (APCs), the fees paid by the author, the author's institution, or their research funder. The acceptance rate at all four EMBO Press journals included in this analysis is between 9% and 13% highlighting the fact that rejected papers do not generate income but require resources.
The EMBO data will inform the Coalition S grouping of leading science funding bodies, which are involved in a major push to make the research they fund open access on publication, under the so-called Plan S, from 2021.

Plan S *is an initiative for Open Access publishing that was launched in September 2018. It requires that, from 2021, scientific publications that result from research funded by public grants must be published in compliant Open Access journals or platforms. The plan is supported by cOAlition S, an international consortium of research funders who have pledged to ignore the prestige of journals when making funding decisions. In some cases, researchers will be able to publish work under more restrictive open licences, when approved by the funder, than was previously allowed.*

Sources: https://www.embo.org/publishing-costs-at-embo

https://sciencebusiness.net/-publishing-costs-open-access

Plan S: https://www.nature.com/articles/d41586-019-01717-2

Coalition S: https://www.coalition-s.org

Calls

ERC Consolidator Grants Call 2020 Open

Deadline: 4 February 2020

The Call for the ERC Consolidator Grants is the last one under Horizon 2020. The ERC Consolidator Grants are for researchers with 7-12 years of research experience after PhD and it is designed to support Principal Investigators at the career stage at which they are consolidating their own independent research team. Up to €2 million are available for projects of up to 5 years duration. Important information on the call is included in the ERC Work Programme 2020 and especially the call-specific Information for Applicants. The proposal templates are available

from the EC Funding and tender opportunities portal once having registered for the call.

For eligibility and how to apply: ERC website.

Call to join the European Reference Networks

Deadline: 30 November 2019

The 2019 call is the first one for new members to join existing 24 European Reference Networks (ERNs). The ERN EYE is the ERN dedicated to Rare Eye Diseases. Anyone wishing to join need to contact one's national representatives in the ERN Board of own Member State. The national representatives provide specific information on their national endorsement process.

Call details: https://ec.europa.eu/2019_call_ERN

Sources: ERN-EYE https://www.ern-eye.eu/ern-eye
https://ec.europa.eu/research/2019_en.pdf

General info on ERNs: https://ec.europa.eu/health/ern_en

Nine Calls for HPB Projects

Deadline: 2 December 2019

The Human Brain Project (HBP) has launched nine calls for new projects to directly contribute to the development of its research infrastructure EBRAINS. The selected projects will increase the scope of its application in terms of innovation, neuroscience and clinical research.

The Human Brain Project (HBP) is building a research infrastructure to help advance neuroscience, medicine and computing. It undertakes targeted research and theoretical studies and explores brain structure and function in humans, rodents and other species; and the ethical and societal implications of its work. The HBP is one of four FET (Future and Emerging Technology) Flagships, the largest scientific projects ever funded by the European Union.

Access the nine calls at: https://www.HBP/-final-phase-opened/

Call for proposals on new infrastructures (ESFRI)

Deadline: 5 May 2020

ESFRI Guide: https://ESFRI-Roadmap2021-Public-Guide.pdf

Health Research Infrastructures: http://esfri

Open Call SC1-HCC-10-2020: Towards a Health Research and Innovation Cloud: Capitalising on Data Sharing Initiatives in Health Research

Deadline: 7 April 2020

Source: https://ec.europa.eu/sc1-hcc-10-2020

Open Call SC1-BHC-06-2020: Digital Diagnostics - Developing Tools for Supporting Clinical Decisions by Integrating Various Diagnostic Data

Deadline: 7 April 2020

Source: https://ec.europa.eu//funding-tenders//sc1-bhc-06-2020

Consultations & Events

WHO - PHARMACEUTICALS

Deadline: 15 January 2020

The World Health Organization (WHO) has drafted a new guideline on data integrity in the production and control of pharmaceuticals.
Contact details for submission in the link below.

Source: https://www.who.int/medicines/data_integrity.pdf

HPRA Public consultation on Strategic Plan 2021-2025

Deadline: 13 December 2019

The Health Products Regulatory Authority (HPRA), Ireland seeks input from stakeholders to help inform the next Strategic Plan for 2021-2025. A short document for this is available at: Strategic Plan 2021-2025 Consultation Feedback Form
Feedback should be sent to: strategy@hpra.ie

Source: https://www.hpra.ie/strategic-plan-2021-2025

The EU EYE continues to be a partner of the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) with a commitment to the B3 Action Group on Integrated care accessible at: https://ec.europa.eu/eip/b3/

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